holds the biological product license, for other than human blood and blood components, and who had control over a distributed product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drugs Evaluation and Research (CDER) as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171, in brief, requires licensed manufacturers of human blood and blood components, including Source Plasma, unlicensed registered blood establishments, and transfusion services, who had control over a distributed product when the deviation occurred, to report to CBER as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Similarly, § 1271.350(b), in brief, requires HCT/P establishments that manufacture non-reproductive HCT/Ps described in § 1271.10 to investigate and report to CBER all HCT/P deviations relating to a distributed HCT/P that relates to the core CGTP requirements, if the deviation occurred in the establishment's facility or in a facility that performed a manufacturing step for the establishment under contract, agreement, or other arrangement. Form FDA 3486 is used to submit BPD reports and HCT/P deviation reports.

Respondents to this collection of information are: (1) Licensed manufacturers of biological products other than human blood and blood components, (2) licensed manufacturers of blood and blood components including Source Plasma, (3) unlicensed registered blood establishments, (4) transfusion services, and (5) establishments that manufacture non-reproductive HCT/Ps regulated solely under section 361 of the PHS Act as described in § 1271.10. The number of respondents and total annual responses are based on the BPD reports and HCT/P deviation reports FDA received in fiscal year 2015. The number of licensed manufacturers and total annual responses under § 600.14 include the estimates for BPD reports submitted to both CBER and CDER. Based on the information from industry, the estimated average time to complete a deviation report is 2 hours, which includes a minimal one-time burden to create a user account for those reports submitted electronically. The availability of the standardized report form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER has developed a Web-based addendum to Form FDA 3486 (Form FDA 3486A) to provide additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested includes information not contained in the Form FDA 3486 such as: (1) Distribution pattern; (2) method of consignee notification; (3) consignee(s) of products for further manufacture; (4) additional product information; (5) updated product disposition; and (6) industry recall contacts. This information is requested by CBER through email notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. At this time, Form FDA 3486A is being used only for those BPD reports submitted under § 606.171. CBER estimates that 5 percent of the total BPD reports submitted to CBER under § 606.171 would need additional information submitted in Form FDA 3486A. CBER further estimates that it would take between 10 to 20 minutes to complete Form FDA 3486A. For calculation purposes, CBER is using 15 minutes.

Activities such as investigating, changing standard operating procedures or processes, and followup are currently required under parts 211 (approved under OMB control number 0910–0139), part 606 (approved under OMB control number 0910–0116), part 820 (approved under OMB control number 0910–0073), and part 1271 (approved under OMB control number 0910–0543) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14	3486	102	5.99	611	2	1,222
606.171	3486	1,738	26.34	45,774	2	91,548
1271.350(b)	3486	97	2.64	256	2	512
Web-based Addendum	[2] 3486A	87	26.31	2,289	.25 (15 minutes)	572
Total						93,854

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of the number of respondents (1,738 × 0.05 = 87) and total annual responses to CBER (45,774 × 0.05 = 2,289).

Dated: May 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13366 Filed 6–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel Pilot

Effectiveness Trials for Treatment, Preventive and Services Interventions (R34)

Date: June 24, 2016.

Time: 11:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, *gavinevanskm@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Fellowship and Dissertation Grants Review Meeting.

Date: June 30, 2016.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892–9606, 301–443–9699, *bursteinme@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Mental Health Services Conflicts (Teleconference).

Date: June 30, 2016.

Time: 12:30 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, *gavinevanskm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: June 1, 2016.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–13310 Filed 6–6–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request, U.S. Nuclear Medicine Technologists Study (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 28, 2016 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact*: Michele M. Doody, Radiation Epidemiology Branch, National Cancer Institute, 9609 Medical Center Drive, Room 7E566, Rockville, MD 20850, or call non-toll-free number 301–414–0308. Or Email your request, including your address to: *doodym@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: U.S. Nuclear Medicine Technologists Study, 0925–0656, Expiration Date 04/30/2015—REINSTATEMENT WITH CHANGE, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: We propose to collect from U.S. nuclear medicine technologists (USNMT) certified after 1980 historical information about nuclear medicine procedures performed, radioisotopes used, related work and safety practices, and places of employment. The primary objectives of the current feasibility effort are: (a) To identify a cohort of nuclear medicine technologists certified after 1980 by the American Registry of Radiologic Technologists (ARRT) and/or the Nuclear Medicine Technologist Certification Board (NMTCB); and (b) to characterize individual organ-specific occupational radiation doses from radioisotope procedures. More recently certified technologists, who specialized in nuclear medicine, are expected to have greater exposures to radioisotopes than the general radiologic technologists in the U.S. Radiologic Technologist (USRT) cohort owing to performing such procedures with greater frequency. The proposed USNMT study would be a direct follow-on to the USRT Study to assess health risks associated with occupational exposure to these much higher-energy radiopharmaceuticals.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 125.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Instrument	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Nuclear Medicine Technologists	Nuclear Medicine Questionnaire	250	1	30/60	125
Total		250	250		125